UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JEANETTE GELBER AND HUGH GELBER,

Plaintiffs,

v.

STRYKER CORPORATION, HOWMEDICA OSTEONICS, AND STRYKER ORTHOPEDICS, INC.,

Defendants.

09 Civ. 1322

ORDER AND OPINION

LORETTA A. PRESKA, Chief United States District Judge:

Plaintiffs, Jeanette and Hugh Gelber, have brought a product liability action against Defendants Stryker Corporation, Howmedica Osteonics, and Stryker Orthopedics, Inc. (collectively "Stryker") to seek damages arising from the failed implantation of an artificial hip prosthesis known as the Trident™ hip replacement system ("Trident"). Defendants have made a motion to dismiss on the grounds that Plaintiffs' claims are preempted by federal law and, to the extent that they are not preempted, Plaintiffs have failed to state a claim for relief pursuant to Fed. R. Civ. P. 12(b)(6). For the foregoing reasons, the Court grants Defendants' motion to dismiss without prejudice.

I. Background

a. Plaintiffs' allegations

The Complaint alleges that in the summer of 2004, Plaintiff Jeanette Gelber received a total right hip replacement. *See* Complaint ¶ 46. She received a Stryker Trident ceramic hip replacement system. Complaint ¶ 47. At some point, Plaintiff heard a squeaking noise from the hip system and experienced pain in her right hip. Complaint

¶ 48. Plaintiff claims that she was informed that the Trident device was defective. Complaint ¶ 49. She alleges that Defendants are liable for her injuries and resulting damages for:

(1) failing to warn of risks;

(2) failing to exercise due care in designing, developing, manufacturing, retailing, distributing, and selling the defective device;

(3) failing to take proper action in petitioning the FDA for a label change to more accurately reflect risks associated with the defective device;

(4) failing to adequately and properly test the defective device, before placing these products on the market;

(5) failing to conduct sufficient testing on the defective device, which if properly performed, would have shown that the product had serious side effects, including, but not limited to, shattering, fracture, squeaking, popping, and causing pain and discomfort in the hip;

(6) failing to adequately warn plaintiff that use of the defective device carried a risk of serious side effects, including but not limited to squeaking, popping, pain and discomfort, and disability;

(7) failing to provide adequate post-marketing warnings or instructions after defendants knew, or should have known, of the significant risks of injuries and events from the use of the defective device;

(8) placing an unsafe product into the stream of commerce; and

(9) failing to act as required under the specific federal requirements outlined above which are applicable to the defective device, including violating federal code and rules.

See Complaint ¶¶ 71-73.

b. FDA Testing of the Trident™ System

The FDA's regulatory regime under the Medical Device Amendments of 1976 established "various levels of oversight for medical devices, depending on the risks they present." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316 (2008). The Trident system has

been classified as a Class III device, which include devices "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury." Medical Device Amendments of 1976 (MDA), 21 U.S.C. § 360c(a)(1)(C).[1]

New Class III devices are subject to a rigorous regime of premarket approval ("PMA") unless they are found to be "substantially equivalent" to a device grandfathered into the MDA. 21 U.S.C. §§ 360c(f)(1), 360e(b)(1). Most new devices enter the market through the process "substantially equivalent" devices, also known as the § 510(k) process. *Riegel*, 552 U.S. at 317; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 479 (1996). Very few devices undergo the much more demanding PMA process—for example, in 2005, only 1% of Class III medical devices were subject to the PMA process. *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 111-12 (2d Cir. 2006), *aff'd* 552 U.S. 312. The Trident was one such device to go through the PMA process.

As has been described in detail in *Riegel*, the PMA process is lengthy—it takes over 1,200 hours to review each application—and involves the submission of volumes of comprehensive information on the device. *Riegel*, 552 U.S. at 318-19. The FDA only grants premarket approval if it finds there is a reasonable assurance of the device's safety and effectiveness. 21 U.S.C. § 360e(d). After approval, the FDA still retains regulatory control over the device. The manufacturer is prohibited from changing "design specification, manufacturing processes, labeling, or any other attribute, that would affect

[1] Class I and Class II devices are subject to much lower levels of review that do not impose specific requirements on devices, and therefore do not fall under *Riegel's* preemption analysis. 21 U.S.C. § 360c(a)(1)(A)-(B).

safety or effectiveness" without first obtaining FDA's approval. *Riegel*, 552 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

Class III devices are also subject to reporting requirements after premarket approval. 21 U.S.C. § 360i. Manufacturers must inform the FDA of new clinical investigations or scientific studies concerning the device, 21 C.F.R. § 814.84(b)(2), and they must "report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred, [21 U.S.C.] § 803.50(a)." *Riegel*, 552 U.S. at 319.

After conducting its PMA review, the FDA approved the Trident as safe and effective for its intended use. *See* Defendants' Memorandum of Law, at 5 (pointing the Court to publicly available documents as evidence Trident's FDA approval). Each change or modification of the Trident has undergone the supplemental PMA process. *Id.*; *see also Horowitz v. Stryker Corp.*, 613 F.Supp.2d 271, 279 (E.D.N.Y. 2009) (in a case involving the same device, the court accepted as undisputed that Trident had been approved by the FDA through the PMA process as a Class III device).

II. Standard of Review for a Motion to Dismiss

In order to "survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face," *Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955). In evaluating a motion to dismiss, a court must "view all allegations raised in the complaint in the light most favorable to the non-moving party . . . and 'must accept as true all factual allegations in the complaint.'" *Newman & Schwartz v. Asplundh Tree Expert Co., Inc.*, 102 F.3d 660, 662 (2d Cir. 1996) (quoting *Leatherman*

v. Tarrant County Narcotics Unit, 507 U.S. 163, 164 (1993)) (citation omitted); *McCarthy*, 482 F.3d at 191. The Court is "not to weigh the evidence that might be presented at a trial but merely to determine whether the complaint itself is legally sufficient." *Goldman v. Belden*, 754 F.2d 1059, 1067 (2d Cir. 1985).

Because the complaint must allege facts which confer a cognizable right of action, "'[t]he issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.'" *York v. Ass'n of the Bar of City of N.Y.*, 286 F.3d 122, 125 (2d Cir. 2002) (citing *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)). The Court must apply a "flexible 'plausibility standard,' which obliges a pleader to amplify a claim with some factual allegations in those contexts where such amplification is needed to render the claim *plausible*." *Iqbal v. Hasty*, 490 F.3d 143, 157-58 (2d Cir. 2007) (referring to the standard under *Twombly*), *rev'd on other grounds by Ashcroft v. Iqbal*, 129 S.Ct. 1937. To that end, the Court will not credit "bare assertions [that] . . . amount to nothing more than a formulaic recitation of the elements of a . . . claim," as such "allegations are conclusory and not entitled to be assumed true." *Ashcroft*, 129 S.Ct. at 1951.

III. Discussion

a. MDA Preemption Clause

The MDA contains an explicit preemption clause, which states that:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from pre-emption. 21 U.S.C. § 360k(b).

In *Riegel*, the Supreme Court interpreted the preemption clause in the MDA as preempting state law claims when (a) the federal government has established specific requirements applicable to the device, and (b) the state law claims are based on requirements that are "different from, or in addition to the federal ones" and relate to the safety and effectiveness of the device. *Riegel*, 552 U.S. at 321-23; *see also* 21 U.S.C. § 360(k)(a)(1). The *Riegel* Court found that because PMA is specific to the device in question and is entirely concerned with the safety and effectiveness of the device, it imposes "specific requirements" that can preempt state common-law duties. *Id.*; *cf. Lohr*, 518 U.S. at 493-94 (rejecting the manufacturer's contention that § 510(k) approval imposed device-specific "requirements.").

But *Riegel* did not close the door to all state-law claims: "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (citing *Lohr*, 518 U.S. at 495). However, *Riegel* did not explore in great detail the nature of "parallel claims" because plaintiffs alleged from the beginning that Medtronic's device violated state tort law notwithstanding compliance with the relevant federal requirements. *Id.*

Riegel specifically found that claims of strict liability, negligence and breach of implied warranty were expressly preempted. 552 U.S. at 320-21. However, there is an absence of Supreme Court guidance on whether the MDA preempts state requirements of general applicability that only incidentally regulate medical devices, e.g., Uniform

Commercial Code or unfair trade practice laws, since *Riegel* refrained from analyzing the exception provided by 21 U.S.C. § 808.1(d)(1). *Riegel*, 552 U.S. at 328-29 ("§ 808.1(d)(1) can add nothing to our analysis but confusion. . . . Neither accepting nor rejecting the FDA's distinction between general requirements that directly regulate and those that regulate only incidentally[,] the regulation fails to alter . . . the outcome of this case").

Post-*Riegel*, courts have struggled to determine whether state-law claims that only incidentally regulate medical devices are still available insofar as they are "parallel" to federal requirements. *Compare Covert v. Stryker Corp.*, 2009 WL 2424559, *5 (M.D.N.C. Aug. 5, 2009) (collecting cases demonstrating "the great majority of courts addressing state-law requirements . . . have found that *Riegel* requires pre-emption) *with Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp.2d 830, 832 ("[S]ome medical device manufacturers . . . have tried recently to stretch *Riegel* beyond recognition by transforming its protection for FDA-approved devices that comply with federal law into a grant of civil immunity for FDA-approved devices that violate federal law.").

This Court finds it persuasive that since the Supreme Court did not carve out a safe harbor for state laws that only incidentally regulate medical devices, the same preemption analysis applies and only those claims that are parallel to federal requirements are permissible. *See Horowitz*, 613 F.Supp.2d at 280; *Covert*, 2009 WL 2424559, *7 (following *Horowitz* and *Parker v. Stryker Corp.*, No. 08-1093, 2008 WL 4716879, at *4 (D.Colo. Oct.22, 2008) in finding that "state-law requirements of general import . . . are subject to federal pre-emption in the same way as those state-law requirements which specifically target the device in question.").

Therefore, the question that this Court must answer is whether Plaintiffs' claims are in fact parallel to federal requirements.

b. Plaintiffs do not object to partial dismissal

Because Plaintiffs have expressed their willingness to discontinue the portion of their claims based upon failure to warn, improper labeling, improper or misleading marketing and/or defective design, the Court considers these claims withdrawn. The Court focuses its attention on the remaining claims of negligence, strict liability, and breach of warranty claims that Plaintiffs claim are premised on alleged violations of the FDA's manufacturing requirements. *See* Plaintiffs' Opposition Memorandum of Law, at 7.

c. Plaintiffs fail to properly allege claims grounded in violations of federal law and/or requirements

Plaintiffs assert that their claims are not preempted because they do not seek to impose different or additional requirements on Defendants. Rather, the claims are based on Defendants' alleged violation of FDA manufacturing requirements and run parallel to federal regulation. Defendants object that Plaintiffs' Complaint does not allege with enough specificity (a) how Defendants violated federal law, or (b) how that violation caused injury to the Gelbers. The Court finds that Plaintiffs have not successfully pled claims that are parallel to federal law and must be dismissed for failure to state a claim.

Plaintiffs direct the Court to a paragraph in the Complaint that states: "Defendants further breached their duties by, among other things . . . failing to act as required under the specific federal requirements outlined above which are applicable to the defective device, including violating federal code and rule." Complaint, ¶ 76. While Plaintiffs

admit that the allegations are "inartfully pled," they argue they are sufficient to provide notice to the Defendants of the basis of the claims.

Plaintiffs rely on *Hofts* for the proposition that "manufacturing defect claims have been held not to be subject to the 'particularity' pleading requirements of Rule 9" and *Lohr* for the proposition that a claim should be allowed to proceed even if "the precise contours of [Plaintiffs'] theory of recovery have not yet been defined . . ." *Hofts*, 597 F.Supp.2d at 838 (citing *Lohr*, 518 U.S. at 495). Other courts have specifically pointed out that *Hofts* is unique in applying such a lax pleading standard. *See, e.g.*, *Horowitz*, 613 F.Supp.2d at 283, n. 5; *Ilarraza v. Medtronic, Inc.*, 677 F.Supp.2d 582, 589 (E.D.N.Y. 2009) ("The court declines to follow [*Hofts*'] court's analysis, and instead follows the larger number of courts that have rejected the sufficiency of pleading nothing more than the violation [of a federal regulation] in support of a parallel claim."); *Covert*, 2009 WL 2424559, *13 (finding more persuasive cases that reject *Hofts* with regard to the pleading standard under *Twombly*).

In line with the majority of courts who have addressed pleading standards in this context, the Court agrees that "Plaintiffs cannot simply incant the magic words [Stryker] violated FDA regulations' in order to avoid preemption." *In re Medtronic*, 592 F.Supp.2d 1147, 1158 (D.Minn. 2009). In this case, Plaintiffs' Complaint is so woefully lacking in factual allegation, it is not a close call. The Court finds that *Twombly* clearly requires more than a conclusory statement that Defendants violated federal code and rule.

Unlike plaintiffs who successfully pled a parallel claim, the Gelbers have not pointed to evidence of device-specific violations of federal law or alleged how those violations have a cognizable link to the Gelbers' injuries. For example, in *Purcel v.*

Advanced Bionics, 2008 WL 3874713, *2-3 (N.D.Tex. Aug. 13, 2008), plaintiffs directed the court's attention to (1) inspection reports and warning letters issued by the FDA to Bionics, documenting federal violations between 2001 and 2005; (2) a voluntary recall issued by Bionics concerning all devices that contained the defective component; and (3) an FDA enforcement action against Bionics for violations of CGMP and premarket approval requirements as a result of the company's failure to notify the FDA of the change in supplier and failing to validate the continued safety and effectiveness of the device.

Even alleging violations of federal law is not sufficient; there must be a cognizable link between the violations and the injury suffered by the plaintiff. For example, in *Horowitz*, plaintiff failed to demonstrate how the particular federal violation she alleges led to the injuries she sustained because she "provides no explanation as to how her Trident System, which was implanted in her body in 2005, relates to investigations conducted by the FDA in 2006 and 2007" nor does she specify whether her device was manufactured in one of the facilities under investigation. 613 F.Supp.2d at 282.

Plaintiffs in this case allege far less than the plaintiff in *Horowitz* because they do not specify the federal violations at the heart of their claims and they do not draw any link between those violations and the injury they suffered. The failure to allege state law claims that are parallel to federal requirements is the primary ground on which the Court grants Defendants' motion to dismiss.

Additionally, the Court recognizes that Plaintiffs fail properly to plead the elements of their claims in other ways as well. For example, to state a manufacturing

defect claim, Plaintiffs must show that the specific product was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction, and that the defect was the cause of plaintiff's injury. *Horowitz*, 613 F.Supp.2d at 283 (citing *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F.Supp.2d 53, 85 (S.D.N.Y. 2001)). By failing to allege any facts surrounding the defectiveness of the Trident system implanted in Mrs. Gelber or a plausible theory for how the device was manufactured improperly, Plaintiffs do not give Defendants any notice of the basis for their manufacturing defect claim.

As for Plaintiffs' breach of express warranty claim, the Complaint is also severely lacking. Even if the Court were to find that "enforcement of an express warranty arising from FDA approved packaging does not establish a requirement that is different from, or in addition to, a federally imposed requirement," Plaintiffs still have an obligation to plead with sufficiency the elements of that claim. *See Delaney v. Stryker Orthopaedics*, 2009 WL 564243, *5 (D.N.J. Mar. 5, 2009) (citing *Michael v. Shiley*, 46 F.3d 1316, 1327 (3d Cir. 1995), *overruled on other grounds*); *cf. Huber v. Howmedica Osteonics Corp.*, 2008 WL 5451072, *3 (D.N.J. Dec. 31, 2008) ("[O]ther courts have divided on the issue of whether or not the MDA preempts express warranty claims.").

In this case, Plaintiffs have failed to allege any affirmative statement made by Defendants regarding the safety or effectiveness of the product on which Plaintiffs actually relied. *See, e.g.*, *Delaney*, 2009 WL 564243, *6. They never state how Defendants' product did not "live[] up to the promises contained on its FDA-approved label" or how such a breach caused their injuries. *See* Plaintiffs' Opposition Memorandum of Law, at 8. The same defect is true of Plaintiffs' breach of implied

warranty claim. Therefore, the Court finds that the failure to meet the *Twombly* pleading standard is another equally firm ground on which to dismiss Plaintiffs' claims.

IV. Conclusion

Because Plaintiffs agreed to discontinue their claims of failure to warn, improper labeling, improper or misleading marketing and/or defective design, the Court considered those claims withdrawn. Defendants' motion to dismiss Plaintiffs' remaining claims [dkt. no. 7] is granted. The Court finds that Plaintiffs failed to allege that their claims are parallel to federal regulations so as to avoid preemption and failed to properly plead the elements of their claims. Because courts have only recently articulated how a plaintiff can successfully plead a parallel claim, Plaintiffs may replead in accordance with this Opinion no later than October 1, 2010.

SO ORDERED:

September 14, 2010

Loretta A. Preska, Chief U.S. District Judge